

Remarks

Claims 1-34 are pending for the Examiner's consideration, including amended claims 8-11, 13, 14, 17-21 and 25. Claims 1-7 and 27-34 have been withdrawn from consideration. No new matter is believed to have been added.

Information Disclosure Statement

An Information Disclosure Statement was filed by Applicants on May 8, 2002, *with copies of all references cited*. A copy of the date-stamped postcard indicating the filing of the references is attached hereto as Exhibit A. The Office Action states that the Information Disclosure Statement "fails to comply with 37 CFR 1.98(a)(2)" and that "the information referred to therein has not been considered."

The Information Disclosure Statement dated May 8, 2002 is being resubmitted concurrently herewith along with *duplicate copies* of the references listed therein. Applicants respectfully request that the disclosed references be made of record in this application, and that the Examiner complete and return an initialed Form PTO-1449.

Applicants also respectfully submit that had the Examiner contacted attorneys for Applicants, duplicate copies of the listed references would have been provided prior to issuance of the first Office Action. Should the Examiner issue a further Office Action based on any of the listed references, Applicants request that such an Office Action should be *non-final* as these references appear to have been lost by the Patent Office.

Claim to Priority

Applicants respectfully request that the Examiner acknowledge the claim to priority to provisional application no. 60/271,745 filed February 28, 2001 on an Office Action Summary under the heading "Priority under 35 U.S.C. §§ 119 and 120."

Claim Rejections

Claims 8-25 were rejected under 35 U.S.C. § 112, ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection respectfully is overcome.

The Office Action states that with respect to claim 8, "it is unclear what element, if any, is partially demineralized." In response, claim 8 has been amended to recite, *inter alia*, "the unitary body further having at least one partially demineralized region."

The Office Action also states that "[w]ith regard to claims 9 and 20, it is unclear how and where the fastener holes are oriented with respect to each other feature of

the plate.” In response, claims 9 and 20 have each been amended to recite, *inter alia*, “a plurality of fastener holes in the unitary body.”

With respect to claim 10, the Office Action states that “it is unclear if the first at least partially demineralized region is related to the other demineralized region set forth in base claim 8.” In response, claim 10 has been amended to recite, *inter alia*, that “the body has a central longitudinal axis, and the at least one partially demineralized region comprises a first at least partially demineralized region that is coaxial with the longitudinal axis.”

The Office Action further states that with respect to claim 11, “the language ‘across the entire length’ is confusing.” Claim 11 has been amended to recite that “the first at least partially demineralized region extends substantially across the unitary body.”

In response to the Examiner’s observation that the limitation “first at least partially demineralized region” is repeated in claims 10 and 13, claim 13 has been amended to provide antecedent basis.

The Office Action also states that “[w]ith regard to claim 10 to 16, it is unclear if the first and second regions of partially demineralized regions are subsets of the at least ‘one partially demineralized region’ of claim 8 or not.” In response, claim 14 has been amended to recite that “the at least one partially demineralized region further comprises at least a second at least partially demineralized region that is disposed transverse to the first at least partially demineralized region.”

In addition, the Office Action states that “[w]ith regard to claim 17, the claim language is confusing since the width should inherently be the thinness of the body so it is unclear what is being modified by the claim language.” In response, claim 17 has been amended to recite that “the body is relatively thin compared to each of the first widths and the second width.”

Finally, with respect to claim 25, the Office Action states that “it is unclear why ‘a first width’ is being claimed since one was set forth in base claim 8.” In response, claim 25 has been amended to recite that “the first width is about 5 mm, and the body has a length of about 15 mm along the central longitudinal axis and a thickness of about 2 mm transverse to the central longitudinal axis.”

Claims 8 and 17-19 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,206,923 to Boyd *et al.* (“Boyd”). The rejection respectfully is overcome.

Applicants’ invention, as presented in amended independent claim 8, is directed to a plate comprising: a unitary body with a pair of portions each having a first width

and a central portion disposed therebetween having a second width, the first width being substantially greater than the second width, and the body being formed of cortical bone; and the unitary body further having at least one partially demineralized region with a third width smaller than the second width, wherein the at least one partially demineralized region confers flexibility to the plate.

Applicants submit that ridges 18, 19, 20, 21 in Boyd, at the least, do not provide a construction with the first width being substantially greater than the second width.

In the Office Action, claims 8-21 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2002/0107570 A1 to Sybert *et al.* (“Sybert”). The Examiner cites to Figs. 1b and 1c, as well as paragraphs 33, 38, 39, and 43 of Sybert. The rejection respectfully is overcome.

Applicants submit that the Sybert does not disclose the construction of amended independent claim 8 comprising, *inter alia*, at least one partially demineralized region with a third width smaller than the second width. Moreover, Applicants submit that Sybert does not disclose the construction of amended independent claim 18 in which the at least one partially demineralized region extends substantially across the second width and is configured with edges extending transverse to a central longitudinal axis of the body. Furthermore, Applicants submit that Sybert does not disclose the construction of amended independent claim 21 in which the body is generally dogbone shaped.

Claims 9-12 and 20 were rejected in the Office Action under 35 U.S.C. § 103(a) as being unpatentable over Boyd in view of U.S. Patent No. 6,458,158 B1 to Anderson *et al.* (“Anderson”). The rejection respectfully is traversed.

With respect to dependent claims 9-12 and 20 which depend from claim 8, it is submitted that these claims at least are patentable not only because of the patentability of the independent claim from which they depend, but also for the totality of features recited respectively therein.

Claims 21-25 were rejected in the Office Action under 35 U.S.C. § 103(a) as being unpatentable over Boyd. The rejection respectfully is traversed.

The Office Action states that “Boyd discloses all of the features claimed but lacks the generally dogbone shape as claimed.” But the Office Action states: “[A]t the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to shape the implant in a generally dogbone shape because Applicants

have not disclosed that the dogbone shape provides some advantage, is used for a particular purpose, or solves a stated problem.” Applicants respectfully disagree.

Applicants’ invention, as presented in amended independent claim 21, is directed to a plate comprising: a unitary body with a pair of portions each having a first width and a central portion disposed therebetween having a second width, the first width being substantially greater than the second width, and the body being formed of cortical bone; and the unitary body further having at least one partially demineralized region, wherein the at least one partially demineralized region confers flexibility to the plate, and wherein the body is generally dogbone shaped.

As stated in the specification of the present application, “dogbone plates may be used, for example, in thin areas of the face where fixation is required.” (Specification, page 16, lines 3-4). Applicants submit that only through impermissible hindsight can Boyd be modified to the advantageous construction recited in claim 21.

With respect to claims 22-25, it is Applicants’ position that the recited dimensions are nonobvious, particularly because such plate embodiments advantageously may be used in maxillofacial applications. Boyd, on the other hand, is directed to implantable devices useful for creating bony fusion particularly in intervertebral spinal fusion. Applicants submit that the dimensioning in claims 22-25 is not obvious from the disclosure of spinal implants in Boyd.

Finally, claim 26 was rejected in the Office Action under 35 U.S.C. § 103(a) as being unpatentable over Boyd in view of U.S. Patent No. 5,084,051 to Törmälä *et al.* (“Törmälä”). The rejection respectfully is traversed.

As stated above, Boyd is directed to implantable devices useful for creating bony fusion particularly in intervertebral spinal fusion.

Törmälä is directed to layered surgical biocomposite material. As disclosed in Törmälä, the biocomposite material contains at least one bioceramic piece (1) (bioceramic component) and at least one material component (2). The material component (2) comprises at least reinforcement elements which have been manufactured of essentially resorbable material like polymer, copolymer, polymer mixture and/or ceramic material. *See, e.g.,* abstract of Törmälä.

Applicants’ invention, as presented in independent claim 26, is directed to an implant comprising a unitary section of cortical bone having a first portion that is mineralized and a second portion that is at least partially demineralized, wherein the mineralized portion includes a plurality of slits to facilitate bending of the unitary section.

Unlike the bioceramic/polymer composite of Törmälä, the implant of pending claim 26 is formed of cortical bone. Moreover, there is no suggestion to change the implant of Boyd with the structure of Törmälä without impermissible hindsight.

Applicants submit that independent claim 26 is patentable over the combination of Boyd in view of Törmälä.

Conclusion

In view of the foregoing, it is believed that all the pending claims are in condition for allowance, which is respectfully requested. If the Examiner does not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues so as to expedite the eventual allowance of the claims.

No fee is believed to be due for this submission. Should any fees be required, however, please charge such fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Date: October 29, 2003

Respectfully Submitted,

Seth A. Watkins
FOR: Brian M. Rothery

Seth A. Watkins Reg. No. 47,169
For: Brian M. Rothery Reg. No. 35,340
PENNIE & EDMONDS LLP
1667 K Street, N.W.
Washington, D.C. 20006
(202) 496-4400

Enclosures